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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,693	11/07/2000	Se-Jin Lee	JHU 1120-15	2065

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EXAMINER	
ANDRES, JANET L	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 05/07/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,693	LEE ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9-22, 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 13 February 2002 in paper no. 11 is acknowledged. Claims 1-29 are pending in this application. Claims 5-8 and 23-26 are withdrawn from consideration as drawn to a non-elected invention. Claims 1-4, 9-22, and 27-29 are examined in light of the species election of SEQ ID Nos: 3 and 4. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Election/Restrictions

2. Applicant continues to traverse the requirement for an election of species. Further traversal is not timely, the restriction requirement having been made final in the Office Action of paper no. 9. Applicant may petition the Commissioner to review the requirement; see 37 C.F.R. 1.1444 and MPEP §818.03(c).

Claim Rejections/Objections Withdrawn

3. The objection to the specification is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained

4. The rejection of claims 1-4, 9-22, and 27-29 as being unpatentable over claims 2-11 of U.S. patent 5827733 under the judicially created doctrine of obviousness-type double patenting and the provisional rejection of the claims as unpatentable over claims 21-23 of 09/628112 are maintained for reasons of record. Applicant may defer responding as requested; however, traversal at time of allowability will not be considered timely.

5. The rejection of claims 1-4, 9-22, and 27-23 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained.

Applicant argues that the specification discloses the signal peptide, prodomain, and mature forms of myostatin. Applicant argues that regions comprising the prodomain of myostatin are inhibitory. Applicant submits that one skilled in the art would have known that Applicant was in possession of promyostatin polypeptides and portions thereof that are inhibitory. Applicant argues that an assay based on determination of SMAD phosphorylation can be used to identify a peptide portion of a promyostatin polypeptide that can affect signal transduction. Applicant concludes that the specification discloses peptide portions of promyostatin that can activate or that can inhibit signal transduction and provides assays to identify portions that can affect signal transduction.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated in the previous office action, the claims encompass peptides that affect all steps in myostatin signaling in all ways. The definition on p. 20 indicated that the claimed molecules are "characterized, in part, by having or affecting an activity associated with the stimulation or inhibition of GDF signal transduction". Applicant has described one inhibitory region and the mature form of the polypeptide. No structural features or characteristics responsible for any other functions are described. No "portions" other than the pro region that would result in inhibition are described. No "portions" other than the mature molecule that would stimulate transduction are described. No regions that would affect signal transduction in any way other than by inhibition of the mature molecule are described. No regions that would otherwise affect stimulation or inhibition, or affect an activity "associated with stimulation or inhibition" are described. Thus one of skill in the art would not conclude that Applicant was in possession of the invention as broadly claimed.

Applicant further argues that an assay based on SMAD phosphorylation could be used to identify the claimed invention. However, an idea for an invention, and an invitation to experiment to implement this invention, does not describe the invention itself. MPEP §2163.05 states that, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. For the reasons set forth above and in the previous office action, the description of the mature form and the pro region of myostatin is not sufficient to describe the genus of all portions of mysostatin having any effect on GDF signaling.

6. The rejection of claims 1-4, 9-22, and 27-29 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims, is maintained.

Applicant argues that the function of a peptide portion is clearly defined. Applicant argues that screening of randomly generated molecules is routine in the art and is unaware of a correlation between expectation of success and whether a screening assay is routine. Applicant argues that it would be routine to make and assay various and numerous peptide portions of promyostatin. Applicants request that the rejection and objection to the specification be withdrawn.

The Examiner notes that there is no objection to the specification corresponding to this rejection.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above and in the previous office action, the definition of "function" includes all means of activation, inhibition, and effects on activation and inhibition. Thus many potential screens are required to make and use Applicant's invention. The screens may be

routine, however, the use of these screens without guidance predictive of success is not routine. To practice Applicant's invention as claimed, one of skill in the art would have to make any and all possible portions of myostatin and assay these for any and all possible effects on signaling and effects associated with signaling. Applicant's disclosure that the pro region is inhibitory and that the C-terminus is the signaling molecule is not sufficient to allow one of skill in the art to predict what other peptide portions, if any, would be "functional' and how they would function. Thus, since the claims are broadly drawn and Applicant has not provided sufficient guidance as to what "peptide portions" would meet the limitations of the claims, it would require undue experimentation for one of skill in the art to make and use the invention as claimed.

7. The rejection of claims 1-4, 9-22, and 27-29 under 35 U.S.C. 112, second paragraph, as indefinite is maintained.

Applicant argues that "peptide portion" and "proteolytic fragment", and "functional peptide portion" are defined and points to the specification. The Examiner agrees that "peptide portion" is clearly defined and this basis of the rejection is withdrawn. However, a "proteolytic fragment" is not defined by reference to any particular protease or any cleavage site, and Applicant's definition further indicates that it need not be generated by proteolysis. The fragment could thus be generated by any protease, including those not yet known in the art, or by any other means, and one of skill in the art would not be able to determine what molecules Applicant intended to encompass. Applicant further argues that "functional peptide portion" is defined. However, the definition encompasses any effect on signaling and any effect associated with signaling. There is no definition of what activities would be considered to be "associated with" signaling; further, the definition indicates that this limitation is only a partial

characterization. Thus the skilled artisan would not be able to determine what molecules had activities "associated with" effects on signaling and what other characteristics might be required.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
May 3, 2002

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER